K052744

DEC 16 2005

510(k) Summary

Submitter:	ACIST Medical Systems, Inc 7450 Flying Cloud Drive, Suite 150 Eden Prairie, MN 55344 USA
Contact Person:	Mr. Al Saalabi Vice President of Quality and Regulatory Affairs Phone: (952) 995-9360 FAX: (952) 941-4648 Al.saalabi@acistmedical.com
Date Prepared:	September 28, 2005
Trade Name:	C2000 Automated Kit Assembly
Classification Name and Number:	Angiographic contrast media injection systems, and its accessories, have been classifieds as Class II devices per 21 CFR 870.1650. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices.
Product Code:	DXT
Predicate Device	The ACIST Angiographic Contrast Management System cleared under K984231.
Device Description:	The C2000 Automated Manifold Assembly Kit is the disposable patient contact intravenous tubing that attaches to Part A via a connector. This kit is contains the patient manifold, saline spike, 3-way pressure stopcock, high pressure line, and a syringe cap. This kit is designed to be connected to the users own pressure monitoring equipment to measure homodynamic waveform.
Intended Use:	The ACIST Angiographic Injection System is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures.
Statement of Technological Comparison	The subject device and predicate device have the following similarities. • The same indication for use; • The same operating principle; • The same basic design; • materials; • The same manufacturing environment; • The same sterilization process; and • The same packaging configurations. In summary, the subject device, as described in this submission is, in the opinion of ACIST Medical, substantially equivalent to the predicate device.
Conclusion:	The subject device, as modified in this submission, is substantially equivalent to the predicate device, ACIST Angiographic Contrast Management System (cleared under K984231.) This conclusion is based upon the similarities of the devices in terms of functional design, indication for use, principles of operation, materials, and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2005

Acist Medical Systems, Inc.
c/o Mr. Al Saalabi
Vice President of Quality and Regulatory Affairs
7450 Flying Cloud Drive, Suite 150
Eden Prairie, MN 55344

Re: K052744
C2000 Automated Manifold Kit
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector & syringe
Regulatory Class: II
Product Code: DXT
Dated: November 18, 2005
Received: November 21, 2005

Dear Mr. Saalabi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Page

510(k) Number (if known): K052744

Device Name: **C2000 Automated Manifold Kit**

Indications for Use:

The ACIST Angiographic Injection System is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures.

Prescription Use __X___ AND/OR Over-the-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Lien

sic... Sign-Off)
...sion of Cardiovascular Devices

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